

REMARKS

This application is amended to correct informalities to better place the application in condition for allowance.

Status of the Claims

Claims 69, 80, 85, 86 and 88-90 are amended as to form, e.g., to correct spelling and typographical errors.

Claims 107 and 108 are amended to include a description of the suction line, so that the expression has antecedent basis. Support may be found, for example, in figure 2, which clearly shows that 4 extends from the suction nozzle 8 upwards to the proximal part of the working duct.

Claim 113 is amended to clarify that the combination comprises two assemblies, each according to claim 59.

Claims 59-62 and 65-117 remain pending.

Claim Objections

Claim 80 was objected to for including bullets.

The bullets have been removed from claim 80, and withdrawal of the objection is respectfully requested.

Claim Rejections-35 USC §112

Claims 104 and 113 were rejected under 35 USC §112, second paragraph, as being indefinite. This rejection is respectfully traversed for the reasons that follow.

Claim 104 was rejected for reciting "the flange" in line 4 without antecedent basis. However, it is respectfully noted that line 1 of claim 104 recites "the stabilizer comprises a flange", and line 3 continues to further define the flange. Thus, "the flange" in line 4 does have antecedent basis.

Claim 113 was rejected for being unclear. This claim has been amended to clarify that the combination comprises two assemblies, each of which is according to claim 59.

Therefore, the claims are definite, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102 and §103

Claims 59, 60, 61, 65-73, 76, 85-92, 96, 105-110, and 113-117 were rejected under 35 USC §102(e) as being anticipated by SOBLE et al. U.S. 6,547,724 (SOBLE).

Claims 62, 74, 75, 81-84, 93, 97, 100-104, 111 and 112 were rejected under 35 USC §103(a) as being unpatentable over SOBLE.

Claims 77-79, 94 and 95 were rejected under 35 USC §103(a) as being unpatentable over SOBLE in view of ABRAMS et al. U.S. 6,740,098 (ABRAMS).

Claims 80 is rejected under 35 USC §103(a) as being unpatentable over SOBLE in view of ABRAMS, further in view of GIFFORD, III U.S. 5,95,504 ("GIFFORD").

Claims 98 and 99 were rejected under 35 USC §103(a) as being unpatentable over SOBLE in view of MOENNING U.S. 5,725,553 (MOENNING).

These rejections are respectfully traversed for the reasons that follow. These rejections are discussed relative to the independent claims, as well as some of the dependent claims that include features that further distinguish the claimed invention.

The General Teachings of SOBLE

SOBLE discloses a device for urologic procedures. The SOBLE device consists of a flexible sleeve 10 and an elongate instrument 50. The flexible sleeve 10 is tubular (Column 4 Lines 49-50). The elongate instrument 50 is slidably (see title and C3 L10) received inside the flexible sleeve.

Referring to C2 L13-17, the objective of SOBLE is to provide effective and efficient means for removing stones and other unwanted materials from cavities accessible by a flexible endoscope. Referring to C2 L17-21, the more general objective of SOBLE is to provide suction means that can remove large targets and is suitable for treatment of cavities in the body accessible by an endoscope.

These objectives are achieved (see C2 L25-36) by providing the sleeve with a side port between the distal and proximal end of the sleeve, the port being connected to a vacuum

source, the sleeve defining a suction channel through which the instrument extends and which is connectable to the suction source. The instrument is retractable in the proximal direction to beyond the port so that the distal part of the suction channel/sleeve (i.e. the part extending distally from the port) is freed from the instrument. Negative pressure applied to the side port only results in suctioning at the proximal end of the sleeve if said distal part of the sleeve is closed by the instrument in combination with a seal 40.

Referring to the title of SOBLE and C2 L42-47, *the essence of SOBLE* is that retracting the instrument up to beyond the port 20 maximises the available cross-section of the suction channel so that effective removal of large targets becomes possible, see C2 L42-47, and the removal capacity is significantly improved.

Referring to C3 L31-36, according to a further embodiment of SOBLE, concurrent irrigation/ventilation may be provided to the treatment side in order to prevent collapse of the cavity during suction. For this purpose a separate irrigation/ventilation channel can be integrated in the sleeve as well. Figures 3A and 3B show two versions of this embodiment with concurrent irrigation:

- Referring to C6 L13-18, figure 3A shows a sleeve 10 with three lumens. Lumen 1 is sized for insertion of the instrument, lumen 3 is the channel for concurrent

irrigation/ventilation and lumen 2 is an additional working channel.

- Referring to C6 L19-21, the lumens can also be arranged substantially co-axial, as shown in fig. 3B which shows centrally the lumen 1 for insertion of the instrument and two outer lumens, one or both of which may be used as irrigation channel.

Considering the essence of SOBLE (i.e., suctioning through the channel for the instrument after withdrawing the instrument) as well as C3 L23-28, the lumen 1 for the instrument serves, on the one hand, as a working channel for the instrument and, on the other hand, as a suction channel (after withdrawing the instrument in proximal direction to beyond the port suction 20. According to a further embodiment of SOBLE, the collapse of the cavity under treatment is, during suctioning, prevented by providing (concurrent with suctioning) enough liquid flow (irrigation) or gas flow (ventilation) through the channel 3 towards the distal end of the sleeve 10.

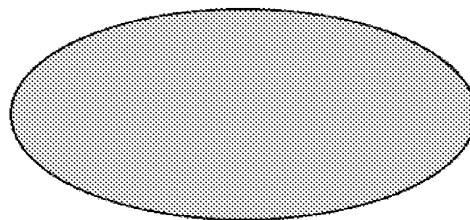
This means that, contrary to the statement made on page 3 of the Office Action, the ducts 3 of Figure 3B are clearly not suction channels, and, thus, also do not provide a suction nozzle on the distal end of the sleeve 10. Instead, the ducts 3 supply fluid (liquid or gas) under overpressure (i.e., not the withdrawal of any fluid by underpressure/suctioning).

Independent Claims 59, 86, 87, 88, 89, 105 and 106

The following features are not anticipated by SOBLE:

- *"one or more suction nozzles running in the shape of a loop"*
and
- *"the loop of said one or more suction nozzles (is provided at the distal end of the working duct and) extends in circumferential direction of the working duct".*

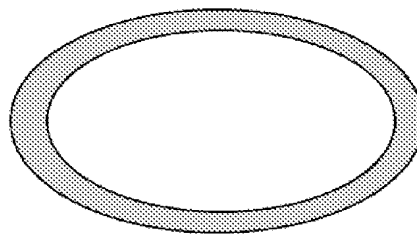
In the embodiment of Figures 3A and 3B of SOBLE the suction channel is formed by lumen 1 having a distal end forming the suction nozzle. In both Figures 3A and 3B, the suction nozzle defines a so called 'span surface'. That is, this is a surface defined by the outer contour of the nozzle and consisting of the entire transverse cross-section defined within the outer contour. Such a surface is indicated in grey in the drawing below, with the dark line defining the outer contour:



single nozzle (grey part)
defining a span surface

In Figure 3B the suction nozzle defines a 'span surface' having the shape of a circle. In Figure 3A the suction nozzle defines a 'span surface' having the shape of a truncated circle.

According to the claimed invention, however, the one or more suction nozzles *'run in the shape of a loop'*. This loop does not define a span surface, but rather an annulus. An example of a single nozzle running in the shape of a loop is shown in the drawing below, in which the single nozzle is oval ring shaped as indicated in grey:



single nozzle (grey part)
running in the shape of a
loop

Thus, it follows that NOBLE does not disclose *"one or more suction nozzles running in the shape of a loop"*, or *'a loop of one or more suction nozzles, which loop extends in circumferential direction of the working duct/sleeve'*.

As all independent claims, i.e. claims 59, 86, 87, 88, 89, 105 and 106, contain the feature *'one or more suction nozzles running in the shape of the loop'* and the feature *'the loop of said one or more suction nozzles extend in circumferential direction of the working duct'*, none of the independent claims 59, 86, 87, 88, 89, 105 and 106 is anticipated by SOBLE.

Moreover, taking into account that according to the independent claims 59, 86, 87, 88, 89, 105 and 106 *"the suction*

nozzles run in the shape of a loop" and "the loop of said one or more suction nozzles is provided at the distal end of the working duct and extends in circumferential direction of the working duct", it also follows that:

- a) the working duct itself is not the suction channel (consequently the distal end face spanned by the distal end of the working duct is not a suction nozzle), and
- b) the suction nozzles (and their connection to the vacuum source) are, according to the independent claims 59, 86, 87, 88, 89, 105 and 106, clearly independent from the lumen defined by the working duct.

Furthermore, according to the independent claims 59, 86, 87, 88, 89, 105 and 106, the working duct is the duct for receiving the instrument as follows from the feature *"the instrument being removably insertable ... into the working duct"*.

Consequently, the difference between SOBLE and the invention can also be expressed as follows: Although SOBLE discloses a working duct which is used for an instrument as well as for suctioning, *SOBLE does not disclose a suction channel/mouth operationally separate from the lumen of the working duct.*

The following feature is non-obvious over SOBLE:

- *"one or more suction nozzles running in the shape of a loop"*

Although no obviousness objections were raised against the independent claims 59, 86, 87, 88, 89, 105 and 106, each of these claims is patentable over SOBLE, as the feature *'one or more suction nozzles running in the shape of the loop'*, is non-obvious over SOBLE.

Taking into account the essence of SOBLE, i.e., *suctioning through the channel for the instrument after withdrawing the instrument*, it is clear that the suction nozzle of SOBLE is by definition the transverse cross-section of the lumen of the instrument channel 1, which is a so called *'span surface'* and does not have the shape of a loop. This suction nozzle being defined by a so called *'span surface'* is according to SOBLE a necessary and indispensable requirement as otherwise the aimed advantage (see C2 L42-47) of maximizing the cross-section for removal of large parts is not achieved.

A loop shaped suction nozzle does a) not allow large parts to be suctioned away effectively and is b) not suitable to serve as channel for an instrument. Such a feature would have rendered the nozzle of SOBLE unsatisfactory for its intended function. Thus, a person having ordinary skill in the art would have been strongly discouraged from modifying SOBLE so that the suction nozzle becomes loop shaped.

Therefore, the feature *'one or more suction nozzles running in the shape of the'* being present in all independent

claims, makes each of the independent claims 59, 86, 87, 88, 89, 105 and 106 non-obvious over SOBLE.

The following features are also non-obvious over SOBLE:

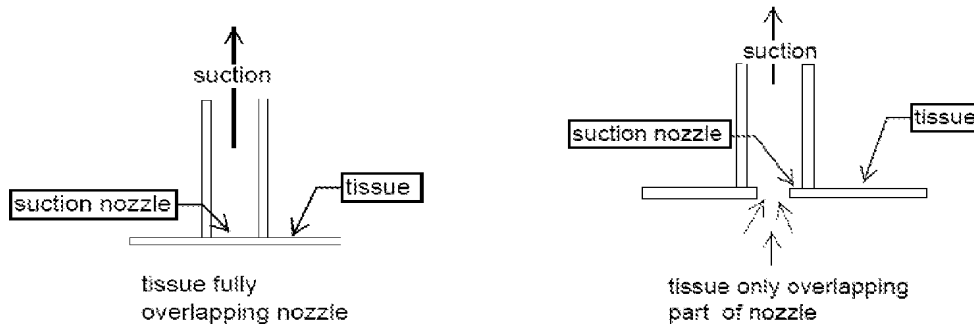
- *"which suction nozzles are operationally connected to the suction source in order to suck tightly to tissue close to and around said passage"*
- and
- *"wherein the loop of said one or more suction nozzles is provided at the distal end of the working duct and extends in circumferential direction of the working duct".*

According to SOBLE, the object and function of the suction channel is to remove stones and other unwanted materials (especially large objects) from a cavity, see C2 L15-17.

The function of the one or more suction nozzles according to the present invention is to suck tightly to vascular tissue surrounding the passage into or around which the instrument is positioned (see lines 3-6 of each of claims 59, 86, 87, 88, 89, 105 and 106). This function cannot be achieved by SOBLE.

SOBLE cannot achieve this function. The suction nozzle of SOBLE is defined by a so called 'span surface' covering the entire cross-section of the suction channel and facing in axial, distal direction. SOBLE's suction nozzle can only stabilize to tissue which is a) located distally in front of SOBLE's sleeve and b) fully overlapping the suction nozzle. In case tissue lying distally in front of SOBLE's sleeve does not fully overlap SOBLE's suction nozzle, as is the case at a passage through or in

vascular tissue, no fixation of SOBLE's sleeve, and, consequently no stabilization, onto tissue occurs at all. Instead, false fluid (liquid and/or gas) is sucked in so that a vacuum can not be established and maintained. This is illustrated in the drawings below:



The right drawing shows SOBLE's sleeve stabilized onto tissue in front of it, which tissue fully overlaps SOBLE's suction nozzle.

The left drawing on shows SOBLE's sleeve having tissue in front of it which only overlaps part of SOBLE's suction nozzle. The arrows shown through the opening in the tissue represents the flow of false fluid being sucked into the nozzle. As a result, there is no fixation onto tissue, and consequently no stabilization.

The claimed invention, however, is able to achieve this function due to both the feature *"which suction nozzles are operationally connected to the suction source in order to suck tightly to tissue close to and around said passage"* and the feature *"wherein the loop of said one or more suction nozzles is provided at the distal end of the working duct and extends in*

circumferential direction of the working duct". Due to 'the loop of suction nozzles extending in circumferential direction of the working duct' the suction nozzles according to the invention allow stabilization of vascular tissue surrounding the passage into or around which the instrument is positioned.

Taking into account that both these features are present in all independent claims and that SOBLE neither discloses nor suggests these features, it follows that each of the independent claims 59, 86, 87, 88, 89, 105 and 106 is non-obvious over SOBLE.

Regardless of the ability of either ABRAMS or GIFFORD to teach that for which it is offered, neither document is able to remedy the shortcomings of SOBLE for reference purposes. As noted above, in order to even approach the claimed invention, one would have had to modify the suction nozzles of SOBLE in a manner that would have rendered them unsatisfactory for their intended purpose.

Therefore, the independent claims 59, 86, 87, 88, 89, 105 and 106, as well as the claims depending from these independent claims, are not rendered obvious by SOBLE alone or in combination with ABRAMS or GIFFORD. Withdrawal of these rejections are respectfully requested.

Dependent Claims 65, 85, 96, 107 and 108

Each of the claims 65, 85, 96, 107 and 108, all depending from claim 59, include features that are neither anticipated by SOBLE nor rendered obvious over SOBLE with or without ABRAMS or GIFFORD.

In SOBLE, the lumen of the sleeve 10 (or channel 1), in which SOBLE's instrument is slidably received, is also the suction channel feeding SOBLE's suction nozzle at the distal end of the sleeve with under-pressure/vacuum. As discussed above, the consequence of this is that SOBLE's suction nozzle is a so called 'span surface' which can grip only tissue which fully overlaps this 'span surface' and which cannot grip vascular tissue in or around a passage into which the instrument is positioned (as is the case according to the invention).

The dependent claims 65, 85, 96, 107 and 108 all have in common that they clearly define that the cylindrical lumen of the working duct is not the channel feeding the suction nozzles with underpressure/vacuum. According to each of these claims there is a passage separate from the cylindrical lumen of the working duct, which passage feeds the one or more suction nozzles with the under-pressure/vacuum.

This provides advantages to the assembly according to the invention. The loop of one or more suction nozzles is

operationally completely separated from the lumen of the working duct. Consequently:

- The loop of one or more suction nozzles provide highly reliable stabilization of vascular tissue surrounding the passage in or around which the instrument is to be positioned.
- The working duct according to the invention can be stabilized independent from the presence of an instrument. The instrument can thus also be removed from the working duct whilst maintaining the stabilization of the working duct onto vascular tissue in or around the passage into which the instrument is to be positioned. Also the stabilization can be achieved before inserting the instrument into the working duct. According to SOBLE it is necessary that the instrument is inserted into the sleeve in order to obtain a seal proximal from the suction port 20. In case the instrument is not inserted before applying the suction force, fluid (air) will be sucked in through the open proximal end of the sleeve.

Now turning to the specific features of each of the claims 65, 85, 96, 107 and 108:

Claim 65

The assembly according to claim 59, wherein at least one axial suction duct that joins the suction source to said one or more suction nozzles is located in the wall of the working duct.

According to this claim the 'passage separate from the cylindrical lumen of the working duct' is an axially extending suction duct which is separate from the cylindrical lumen of the working duct as it is located in the wall of the working duct. This axial suction duct joins the suction source to the one or more suction nozzles.

Claim 85

The assembly according to claim 59, wherein the stabilizer is provided with a ring shaped suction body comprising said one or more suction nozzles running in the shape of said loop, wherein the loop extends in circumferential direction of the suction body, and wherein the suction source comprise a suction line opening into a suction passage formed in the interior of the suction body, which suction passage, in turn, is in communication with the suction nozzle.

According to this claim the 'passage separate from the cylindrical lumen of the working duct' is a suction line together with a suction passage. The loop of suction nozzles being operationally separated from the lumen of the working duct is further emphasized by the (loop of) suction nozzles being arranged on a ring shaped suction body provided to the stabilizer.

Claim 96

The assembly according to claim 59, wherein the working duct is a hollow double walled working duct.

According to this claim the 'passage separate from the cylindrical lumen of the working duct' is the cavity provided by the hollow in the double walled working duct. The 'passage separate from the cylindrical lumen of the working duct' thus extends inside the (double walled) wall of the working duct.

Claim 107

The assembly according to claim 59, wherein the suction line is operationally separated from the cylindrical lumen defined by the wall of the working duct.

According to this claim the 'passage separate from the cylindrical lumen of the working duct' is a suction line which is operationally separated from the cylindrical lumen of the working duct.

Claim 108

The assembly according to claim 59, wherein the suction line comprises a suction passage formed in the interior of the wall of the working duct, which passage extends from the suction nozzles up to a proximal part of the working duct.

According to this claim the 'passage separate from the cylindrical lumen of the working duct' is a suction passage formed in the interior of the wall of the working duct and extending from up to the suction nozzles.

Thus, each of the dependent claims 65, 85, 96, 107 and 108 is neither anticipated by SOBLE nor rendered obvious over SOBLE.

Therefore, withdrawal of the rejection of the dependent claims 65, 85, 96, 107 and 108 is respectfully requested.

Dependent Claims 90 and 87

Each of the claims 90 and 87 is not disclosed by SOBLE, is non-obvious over SOBLE as well as non-obvious over SOBLE and ABRAMS and/or GIFFORD.

Claim 90 is dependent from claim 59. Claim 87 is independent but contains the complete wording of claim 90. These claims share the following feature:

*wherein the assembly further comprises at least one of
(i) a guide on the stabilizer on which the instrument
stop is provided such that it can slide along the guide
and with respect to which the instrument stop can be
locked and
(ii) a guide on the instrument on which the stabilizer
stop is fitted such that it can slide along the
instrument and with respect to which the stabilizer can
be locked,
wherein the guide is provided at the proximal end of the
working duct and has a direction of extension essentially
transverse to the loop shape.*

In short, this feature says that the assembly comprises a guide which is provided with a slidable stop which can slide along the guide and can be locked to the guide. This guide can be provided on either the stabilizer or the instrument. In case the guide is provided on the stabilizer, the slidable stop is the instrument stop. In case the guide is provided on the instrument, the slidable stop is the stabilizer stop.

The stops of the present invention define the position of the stabilizer with respect to the instrument unambiguously in case they contact each other.

Referring to page 3 of the Office Action, SOBLE would disclose stops in the form of the proximal end of sleeve 10 and item 50. Although we disagree in this respect, it for the moment is preferred to assume the correctness of this assumption of the examiner. Assuming that the proximal end of sleeve 10 and item 50 on the instrument (fig 1+2 of SOBLE) function as stops, the proximal end of the sleeve 10 would be the so called 'instrument

stop' of the invention and item 50 would be the so called stabilizer stop of the invention.

However:

- a) the proximal end of sleeve 10 (instrument stop) can not be moved with respect to the sleeve (stabilizer) so that the sleeve (stabilizer) consequently also has no guide along which the proximal end of sleeve 10 (instrument stop) can be moved; and
- b) item 50 (stabilizer stop) can not be moved with respect to the instrument so that the instrument consequently also has no guide along which item 50 (stabilizer stop) can be moved.

The above cited feature (claim 90) thus is not disclosed by SOBLE.

In as far as the clamp 42 of SOBLE would be considered to constitute a stop, it is noted that this is incorrect. This because the clamp of SOBLE clearly does not unambiguously define the position of SOBLE's sleeve 10 with respect to SOBLE's instrument. Referring to C5 L9 of SOBLE, clamp 42 provides an interference fit. This interference fit has the function to provide a seal but allows axial movement of the sleeve with respect to the instrument as also follows from C7 L15 in which an alternative interference fit by constrictor 70 is described. Also this constrictor 70 serves the purpose of sealing and does not

prevent axial movement of the sleeve with respect to the instrument. On the contrary, this axial movement through the interference fit is according to SOBLE clearly allowed as the instrument and sleeve are according to SOBLE required to be slidable with respect to each other. The interference fit of SOBLE thus clearly can not be considered to be a stop and also does not unambiguously define the position of the sleeve with respect to the instrument.

Claims 90 and 87 thus are clearly not disclosed by SOBLE.

Considering that a) a slidable stop allowing adjustment of its position along a guide is not disclosed in SOBLE, b) is also not disclosed in the other cited documents, c) is also not suggested by SOBLE or any other cited documents, and d) provides clear advantages as extensively discussed in earlier replies, it follows that Claims 90 and 87 thus are clearly non-obvious.

Therefore, withdrawal of the rejection of claims 87 and 90 is respectfully requested.

Conclusion

In view of the formal changes to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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